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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,294	05/15/2001	Carlo Croce	CRO01-NP007	1905

7590

06/05/2002

THOMAS JEFFERSON UNIVERSITY
1020 Walnut Street - Suite 630
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EXAMINER

DUFFY, PATRICIA ANN

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 06/05/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/855,294

Applicant

Croce et al

Examiner

Patricia A. Duffy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-3, drawn to an isolated nucleic acid encoding a human Nit2 protein, classified in class 536, subclass 23.1.
 - II. Claims 4-5, drawn to an isolated human Nit2 protein, classified in class 530, subclass 350.
 - III. Claim 6, drawn to an antibody that binds a human Nit2 protein, classified in class 530, subclass 387.1.
 - IV. Claims 7-9, drawn to an isolated nucleic acid encoding a mouse Nit2 protein, classified in class 536, subclass 23.1.
 - V. Claims 10-11, drawn to an isolated mouse Nit2 protein, classified in class 530, subclass 350.
 - VI. Claim 12, drawn to an antibody that binds a mouse Nit2 protein, classified in class 530, subclass 387.1.
 - VII. Claims 13-14, drawn to an isolated *S. pombe* Nit2 protein, classified in class 530, subclass 350.
 - VIII. Claim 15 drawn to an antibody that binds a *S. pombe* Nit2 protein, classified in class 530, subclass 387.1.
 - IX. Claims 16-17, drawn to an isolated *S. cerevisiae* Nit3 protein, classified in class 530, subclass 350.
 - X. Claim 18, drawn to an antibody that binds an *S. cerevisiae* Nit3 protein, classified in class 530, subclass 387.1.

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- XI. Claims 19-21, drawn to an isolated nucleic acid encoding an *X. laevis* Nit1 protein, classified in class 536, subclass 23.1.
- XII. Claims 22-23, drawn to an isolated *X. laevis* Nit1 protein, classified in class 530, subclass 350.
- XIII. Claim 24, drawn to an antibody that binds an *X. laevis* Nit1 protein, classified in class 530, subclass 387.1.
- XIV. Claims 25-26, drawn to an isolated *S. pombe* Nit1 protein, classified in class 530, subclass 350.
- XV. Claim 27 drawn to an antibody that binds a *S. pombe* Nit1 protein, classified in class 530, subclass 387.1.
- XVI. Claims 28-29, drawn to an isolated *S. cerevisiae* Nit2 protein, classified in class 530, subclass 350.
- XVII. Claim 30 drawn to an antibody that binds a *S. cerevisiae* Nit2 protein, classified in class 530, subclass 387.1.
- XVIII. Claim 31 drawn to a method of identifying a Nit2 binding compound that is a Fhit mimic, classified in class 435, subclass 7.8.
- XIX. Claim 32 and 35 drawn to an Fhit mimic, classified in class 536, subclass 1.11.
- XX. Claims 33-34 drawn to an method of treating a disease state with the Fhit mimic, classified in class 514, subclass 23.
- XXI. Claim 36 drawn to a method of identifying a Nit2 binding compound that is a Fhit antagonist, classified in class 435, subclass 7.8.
- XXII. Claim 37 and 40 drawn to an Fhit antagonist, classified in class 536, subclass 1.11.

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XXIII. Claims 38-39 drawn to an method of treating a disease state with the Fhit antagonist, classified in class 514, subclass 23.

2. The inventions are distinct, each from the other because of the following reasons:

Groups I, IV and XI are drawn to different nucleic acid products. The nucleic acid products are distinct each from the other as claimed because they are from different origins (human versus mouse versus frog) and have different primary sequences. As such, the searches are non-overlapping and a search restricted to human would not reveal art on the mouse. In view of the different origins and different primary structures, each nucleic acid drawn to different mammalian species are distinct as claimed.

Groups II, V, VII, IX, XII, XIV and XVI are drawn to different protein products. The protein products are distinct each from the other as claimed because they are from different origins (human versus mouse versus *S. pombe* versus *S. cerevisiae* versus *X. Laevis*), have different primary sequences and are drawn to different proteins (Nit1, Nit2 or Nit3). As such, the searches are non-overlapping and a search restricted to human would not reveal art on the mouse. In view of the different origins and different primary structures, each protein drawn to different mammalian species are distinct as claimed and each protein drawn to different Nit proteins are distinct as claimed.

Groups III, VI, VIII, X, XIII, XV and XVII are drawn to different antibody products. The claimed antibodies that bind these different protein products are also distinct as claimed because they bind and interact with the distinct protein products as set forth directly above.

Groups I-XVII, XIX and XXII are drawn to different products. The claims of Group I and IV are drawn to a polynucleotides, those of Groups II, V, VII, IX, XII, and XIV are drawn to a polypeptides, that of Group III, VI, VIII, X, XIII, XV, and XVII to

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antibodies, those of Group XIX to Fhit mimics and that of Group XXII to Fhit antagonists. The inventions can be shown to be distinct because they are made by different methods and because they are physically and functionally distinct chemical entities. The search for an antagonist would not encompass the search for a mimic because they have opposite functional effects.

Groups XIX and XX are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the mimic can be used in materially different methods such as an affinity binder on a matrix to purify the protein, as a control in a heterologous binding assay.

Groups XXII and XXIII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antagonist can be used in materially different methods such as an affinity binder on a matrix to purify the protein, as a control in a binding assay, or as an imaging agent for detection of Nit proteins *in vivo* or *in vitro*.

Groups XVIII, XX, XXI, and XXIII are drawn to distinct methods which differ in the method objectives, method steps and in the reagents used. The claims of Group XVIII are drawn to a method of screening for mimics using Nit2 whereas the claims of Group XXI are drawn to methods of screening for antagonists. The claims of Group XX are drawn

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to a method of treatment using a Fhit mimic whereas the claims of Group XXIII are drawn to treatment comprising administering an antagonist. The search for methods of treatment using an antagonist would not encompass the search for a mimic because they have opposite functional effects and presumably different structures. Further, the mimics are not required for use in the method of treating with the antagonist and *vice versa*. Similarly, methods of screening for mimics are different from that screening for antagonists because the observed outcome is inapposite. Therefore, search for mimics does not overlap with the search for antagonists. As such, each of the methods are distinct each from the other as claimed.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper. Because these inventions are distinct for the reasons given above and in cases the inventions of the Groups require non-coextensive literature searches, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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6. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

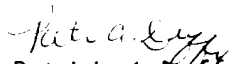
Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Tuesday-Saturday from 10:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D.

June 4, 2002


Patricia A. Duffy, Ph.D.
Primary Examiner
Group 1600